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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,704	04/23/2001	Shoukat Dedhar	KINF001CON2	5167
24353	7590	10/26/2004	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVE SUITE 200 EAST PALO ALTO, CA 94303			GIBBS, TERRA C	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 10/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/840,704

Applicant(s)

DEDHAR ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-10 and 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-10 and 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is a response to Applicants Amendment and Remarks filed August 5, 2004.

Claims 1 and 10 have been amended. Claims 1, 4-10, and 13-18 are pending.

Claims 1, 4-10, and 13-18 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed February 5, 2004, claims 1, 4-10, and 13-18 were rejected under 35 U.S.C. 102(b) as being anticipated by Heraud et al. (Journal of Biological Chemistry, 1998 Vol. 273:17917-17823). **This rejection is maintained** for the reasons of record set forth in the Office Action mailed February 5, 2004.

Response to Arguments

In response to this rejection, Applicants argue that Heraud et al. is not prior art because the instant application claims priority to provisional application 60/009,074, filed December 21, 1995; and to USSN 08/752,345, filed November 19, 1996.

Applicant's arguments have been fully considered, but are not found persuasive because the instant application is a continuation of U.S. Patent Application Ser. No. 09/566,906, filed May 9, 2000, now issued as U.S. Patent No. 6,369,2050, which is a divisional of U.S. Patent

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Application No. 09/390,425, filed September 3, 1999, now issued as U.S. Patent No. 6,338,958, which is a continuation-in-part of U.S. Patent Application No. 08/955,841, filed October 21, 1997, now issued as U.S. Patent No. 6,013,782, which is a continuation-in-part of U.S. Patent application No. 08/752,345, filed November 19, 1996, now abandoned, which claims priority to Provisional Patent Application No. 60/009,074, filed December 21, 1995.

The instant claims are drawn to a method of inhibiting or preventing inflammation in an *in vitro* model for inflammation, comprising administering a compound that inhibits integrin linked kinase. When reviewing the parent applications for support for the term, "an *in vitro* model for inflammation" no specific or inherent support can be found. In fact, U.S. Patent application No. 08/752,345, and Provisional Patent Application No. 60/009,074 do not appear to mention the language "*in vitro* model". While U.S. Patent application No. 08/752,345, and Provisional Patent Application No. 60/009,074 claim an *in vivo* method of treating a disease in a mammal comprising administering an inhibitor of a serine/threonine kinase, such as ILK, this method does not support an *in vitro* model for inflammation, as now claimed. Parent Applications 09/566,906, 09/390,425, and 08/955,841 recite the term "*In vitro* Models for ILK Function", however, no support could be found for the term "*in vitro* model for inflammation". Therefore, the instant claims have been awarded priority of the filing date of the instant application, March 23, 2001.

In this regard, Heraud et al. is prior art because it was published more than a year prior to filing of the instant application, March 23, 2001.

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In the previous Office Action mailed February 5, 2004, claims, 1, 4-7, 9, 10, 13, 14, 15, 16 and 18 were rejected under 35 U.S.C. 102(b) as being anticipated by Norman et al. (Journal of Medicinal Chemistry, 1996 Vol. 39:1106-1111). **This rejection is maintained** for the reasons of record set forth in the Office Action mailed February 5, 2004.

Response to Arguments

In response to this rejection, Applicants argument is two-fold. First, Applicants argue that Norman et al. is not prior art because the instant application claims priority to provisional application 60/009,074, filed December 21, 1995; and to USSN 08/752,345, filed November 19, 1996. Second, Applicants argue that the present claims recite an *in vitro* model for inflammation. Applicants argue that Norman et al. evaluate wortmannin with *in vivo* tumor models, and against a breast cancer cell line. Applicants contend that one of skill in the art could not interpret the term "*in vitro* model for inflammation" as including isolated tumor cells, in the absence of leukocyte mediators of inflammation.

Applicant's arguments have been fully considered, but are not found persuasive. Regarding Applicants first argument, as discussed above, the instant claims have been awarded priority of the filing date of the instant application, March 23, 2001, since parent applications contain no specific or inherent support for an *in vitro* model for inflammation.

In this regard, Norman et al. is prior art because it was published more than a year prior to filing of the instant application, March 23, 2001.

Regarding Applicants second argument, the present claims recite an *in vitro* model for inflammation. The term "an *in vitro* model for inflammation" has not been defined in the instant

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specification as filed. Therefore, the term “an *in vitro* model for inflammation” has been given its broadest reasonable interpretation, and includes the breast cancer cell line, as taught in Norman et al., since Greten et al. (Cell, 2004 Vol. 118:285-296) have recently shown a molecular link between inflammation and cancer (see Abstract). Applicants offer opinionated evidence that one of skill in the art could not interpret the term “an *in vitro* model for inflammation” as including isolated tumor cells, since “inflammation”, as Applicants define, is the “reaction of the body to injury or to infectious, allergic, or chemical irritation”. However, applicants contention that one of skill in the art could not interpret the term “an *in vitro* model for inflammation” as including isolated tumor cells is unfounded since Greten et al. have recently shown a molecular link between inflammation and cancer (see Abstract). Applicants have not presented any experimental data showing that isolated tumor cells would not represent an *in vitro* model for inflammation. Further, the term “an *in vitro* model for inflammation” has not been defined in the instant specification and Applicants arguments do not factually established that one of skill in the art could not interpret the term “an *in vitro* model for inflammation” as including isolated tumor cells. Greten et al. et al. have recently shown a molecular link between inflammation and cancer, and thus the term has been interpreted broadly, and includes the breast cancer cell line, as taught in Norman et al.

In this regard, Norman et al. anticipate claims 1, 4-7, 9, 10, 13, 14, 15, 16 and 18.

Applicant's amendment necessitated the new ground(s) of rejection presented below:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-10, and 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Krymskaya et al. (American Journal of Physiology, 1999 Vol. 277:L65-L78) as evidenced by Johnson et al. (Trends Pharmacol Sci., 1997 Vol. 18 :288-292). **This is a new rejection.**

Krymskaya et al. disclose the effects ILK inhibitors, wortmannin and LY-294002, on airway smooth muscle cells.

Johnson et al. disclose airway smooth muscle cells can participate in and coordinate the inflammatory response (see Abstract). Johnson et al. further disclose that by expressing adhesion molecules, the airway smooth muscle cell acts as a site for inflammatory cell recruitment, thereby potentiating airway inflammation... thus, airway smooth muscle plays important roles in the generation and regulation of both the inflammatory and the structural components of the pathological changes seen in asthma (see page 292, last paragraph).

Therefore, the airway smooth muscle cells taught by Krymskaya et al. represent an *in vitro* model for inflammation as evidenced by Johnson et al. Further, the airway smooth muscle cells, treated with ILK inhibitors, wortmannin and LY-294002, as taught by Krymskaya et al., would inherently inhibit inflammation, as recited in the instant claims, absent evidence to the contrary.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-10, and 13-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The instant application is a continuation of U.S. Patent Application Ser. No. 09/566,906, filed May 9, 2000, now issued as U.S. Patent No. 6,369,2050, which is a divisional of U.S. Patent Application No. 09/390,425, filed September 3, 1999, now issued as U.S. Patent No. 6,338,958, which is a continuation-in-part of U.S. Patent Application No. 08/955,841, filed October 21, 1997, now issued as U.S. Patent No. 6,013,782, which is a continuation-in-part of U.S. Patent application No. 08/752,345, filed November 19, 1996, now abandoned, which claims priority to Provisional Patent Application No. 60/009,074, filed December 21, 1995.

The instant claims are drawn to a method of inhibiting or preventing inflammation in an *in vitro* model for inflammation, comprising administering a compound that inhibits integrin linked kinase. When reviewing the parent applications for support for the term, "an *in vitro* model for inflammation" no specific or inherent support can be found. In fact, U.S. Patent application No. 08/752,345, and Provisional Patent Application No. 60/009,074 do not appear to mention the language "*in vitro* model". While U.S. Patent application No. 08/752,345, and

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Provisional Patent Application No. 60/009,074 claim an *in vivo* method of treating a disease in a mammal comprising administering an inhibitor of a serine/threonine kinase, such as ILK, this method does not support an *in vitro* model for inflammation, as now claimed. Parent Applications 09/566,906, 09/390,425, and 08/955,841 recite the term “*In vitro* Models for ILK Function”, however, no support could be found for the term “*in vitro* model for inflammation”.

The instant specification, at page 25, line 4, recites, “In vitro Models for ILK Function”. However, the instant specification does not have support for the term “an *in vitro* model for inflammation”.

Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP § 2163.06 which states, when filing an amendment, an applicant should show support in the original disclosure for new or amended claims (See MPEP § 714.02 and § 2163.06).

Applicant is required to cancel the new matter in the reply to this Office Action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (571) 272-0758. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg
October 19, 2004

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
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